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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,973	11/07/2006	David Louis Feldman	33687-US-PCT	3773
1095 7550 04/21/2010				
NOVARTIS				
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3				
EAST HANOVER, NJ 07936-1080				
EXAMINER				
FINN, MEGHAN R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
04/21/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/592,973

**Applicant(s)**

FELDMAN ET AL.

**Examiner**

MEGHAN FINN

**Art Unit**

1614

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1 and 3.

Claim(s) withdrawn from consideration: 2 and 4-10.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Meghan Finn/  
Examiner, AU 1614

/James D Anderson/  
Primary Examiner, Art Unit 1614

Continuation of 11, does NOT place the application in condition for allowance because: Applicant's request for reconsideration of the present application with regard to the rejections under 35 U.S.C. 103(a) has been made.

Applicant has submitted amendment of the claims changing claim 1 so that it now reads upon a pharmaceutical composition "consisting essentially of" an effective amount of a renin inhibitor. This amendment has been entered however, the previous rejection still applies as explained below. The position of the office remains the same that the rejection of claims 1 and 3 over Webb et al. is proper and is maintained.

Applicant has stated in their response that they amended the claims to "consisting essentially of" the renin inhibitor and argues that this overcomes the prior art of Webb et al. because they teach the renin inhibitor plus a anti-diabetic agent. The phrase "consisting essentially of" limits the scope of the claims to the specified materials or steps and "those that do not materially affect the basic and novel characteristics of the invention" (see MPEP 2111.03, transitional phrases). Applicant has not disclosed what effects the novel and basic function and it would be obvious to one of skill in the art that anti-diabetic agents would not effect a renin inhibitor which mainly works at treating hypertension. Webb et al. combines the two for treatment of diabetes, which is the same purpose of the instant application but these agents would be expected to work in different ways. Anti-diabetic agents would be focused at controlling blood sugar, such as insulin sensitizers which are taught in Webb et al., and the renin inhibitor would treat hypertension and improve microalbuminuria (page 4 of Webb et al.). Additionally, applicant teaches that the renin inhibitor can be combined with other agents including oral hypoglycaemic agent (page 11 of specification, option xi) which is an anti-diabetic agent and thus applicant indicates that inclusion of such agents would not materially affect but are included in the novel function of the invention. Thus one of skill in the art would not believe these agents to materially affect the basic and novel characteristics of the renin inhibitor and they would be included in the scope of the instant claims. Thus the final rejection mailed December 2, 2009 is maintained.

In absence of any additional arguments or remarks regarding the patentability of the claims pending at the time of the final rejection, the claims remain rejected for the reasons of record previously set forth in the final rejection of December 05, 2008. .